



November 16, 2020

VIA E-FILING

The Honorable Leonard P. Stark
J. Caleb Boggs Federal Building
844 N. King Street
Room 6124, Unit 26
Wilmington, DE 19801-3556

RE: Becton, Dickinson and Company, et al. v. NeuMoDx Molecular, Inc.
C.A. No. 19-cv-1126-LPS

Dear Chief Judge Stark,

Pursuant to paragraph 9 of the Scheduling Order (D.I. 55), Defendant NeuMoDx Molecular, Inc. ("NeuMoDx") submits this letter in support of its unopposed motion to amend its answer to Plaintiffs' amended and supplemental complaint.

Plaintiffs filed their original complaint June 18, 2019 asserting six patents. (D.I. 1.) Defendant filed its Answer on August 9, 2019, and then its Amended Answer on October 4, 2019. (D.I. 15.) After obtaining leave of the Court, Plaintiffs filed their Amended and Supplemental Complaint ("Amended Complaint") on May 15, 2020, asserting seven additional patents. (D.I. 54.) On July 16, 2020, Defendant filed its Answer, Affirmative Defenses and Counterclaims to Defendants' Amended and Supplemental Complaint ("Answer to Plaintiffs' Amended Complaint"). (D.I. 59.)

In correspondence between the parties, Plaintiffs alleged that Defendant's Answer to Plaintiffs' Amended Complaint exceeds the permissible scope allowed by the Court's June 24, 2020 order. (D.I. 52.) While Defendant's Amended Answer included prior-art based invalidity defenses and an improper inventorship defense for the seven new patents, Plaintiffs contend that Defendant should have sought leave of the Court to (i) identify additional prior art asserted against the original patents, and (ii) the improper inventorship defense asserted against the original patents. While Defendant disagrees, to resolve the issue and move forward, Defendant agreed to seek leave of the Court to file the attached version of its Amended Answer to Plaintiffs' Amended Complaint.

The parties conferred and Plaintiffs' agreed that they would not oppose Defendants' motion for leave. Per the Court's practice, Defendant attaches both (1) a clean version of Defendant's proposed Amended Answer to Plaintiffs' Amended Complaint, and (2) a black-line version of Defendant's proposed Amended Answer to Plaintiffs' Amended Complaint compared against Defendants' October 4, 2019 Amended Answer (D.I. 15) filed prior to Plaintiffs' Amended Complaint.

Leave to amend "should be freely give[n] when justice so requires." Fed. R. Civ. P. 15(a)(2). The decision to grant or deny leave to amend lies within the discretion of the court. See *Foman v. Davis*, 371 U.S. 178, 182 (1962); *In re Burlington Coat Factory Secs. Litig.*, 114

F.3d 1410, 1434 (3d Cir. 1997). The Third Circuit has adopted a liberal approach to the amendment of pleadings. *See Dole v. Arco*, 921 F.2d 484, 487 (3d Cir. 1990.) In the absence of undue delay, bad faith, or dilatory motives on the part of the moving party, the amendment should be freely granted, unless it is futile or unfairly prejudicial to the non-moving party. *See Foman*, 371 U.S. at 182; *In re Burlington*, 114 F.3d at 1434.

Good cause to amend exists here. Defendant's motion is timely. It is still early in this case, Plaintiffs' filed their Amended Complaint on May 15, 2020, fact discovery is still in its early stages, the parties are in the process of claim construction, and the deadline in the Scheduling Order for amending pleadings is not until March 5, 2021. A motion for leave to amend filed "within the deadline set forth in the scheduling order for amending pleadings . . . generally precludes a finding of undue delay." *Boston Sci. Corp., et al v. Edwards Lifesciences Corp. et al*, No. 16-275-SLR-SRF, D.I. 103 (Feb. 28, 2017).

Defendant's motion is made in good faith. Defendant filed its original Amended Answer back on October 4, 2019. (D.I. 15.) Since then, Defendant has worked and is continuing to work diligently to pursue its defenses. Defendant's proposed amendments are largely to (i) respond to the new allegations in Plaintiffs' Amended Complaint, (ii) supplement its invalidity counterclaims for the '308, '069, '103 and '787 patents to reflect additional prior art and invalidity positions developed and set forth since filing of NeuMoDx's original Amended Answer on October 4, 2019 (including the prior art identified in NeuMoDx's IPR petitions for the '308, '069, '103 and '787 patents); (iii) add an improper inventorship defense discovered after filing its amended answer back on October 4, 2019 as part of its continuing investigation into Plaintiffs' patents and Plaintiffs' allegations, and (iv) add a license defense that became applicable after Defendant NeuMoDx was acquired as a wholly owned subsidiary by Qiagen.

Defendant's proposed amendments would not prejudice Plaintiffs. Plaintiffs amended their complaint to add seven patents, the parties exchanged initial contentions, the parties are in the early stages of fact discovery, and the parties are currently in the process of claim construction. Additionally, Defendant's present motion is filed well before the March 2021 deadline to amend pleadings. *See, e.g., Butamax Advanced Biofuels LLC v. Gevo, Inc.*, No. 11-54-SLR, 2012 WL 2365905, at *2 (D. Del. June 21, 2012) (holding that a motion to amend filed on the deadline for amended pleadings was "filed timely and, therefore, there can be no unfair prejudice to defendant."). Defendant's proposed amendments are likewise not futile, as they are invalidity defenses that identify specific prior art, specific inventorship errors, specific license agreements, and go to the heart of the case.

We are available at the Court's convenience should Your Honor have any questions.

Respectfully submitted,

/s/ Brian E. Farnan

Brian E. Farnan

cc: Counsel of Record (Via E-Mail)